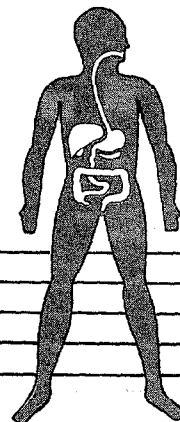


# Digestive Disease National Coalition



9 6 1 2 '00 DEC -6 AM 12

507 Capitol Court, N.E., Suite 200, Washington, D.C. 20002  
(202) 544-7497 (202) 546-7105 - Fax

## EXECUTIVE COMMITTEE

Chairman  
NANCY NORTON

President  
MAURICE CERULLI, M.D.

Vice-Chairman  
PETER BANKS, M.D.

Secretary  
MAUREEN WRIGHT, RN, CGRN

Treasurer  
LINDA KING AUKETT

Members-at-Large  
CARLA H. GINSBURG, MD  
THELMA KING THIEL  
MICHAEL DOLAN  
JAMES DEGEROME, MD

November 20, 2000

Dockets Management Branch  
Food and Drug Administration  
HFA-305  
Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

Re: docket # OOP-1499/CP1

## MEMBERS

American Association for the  
Study of Liver Disease  
American College of  
Gastroenterology  
American Gastroenterological  
Association  
American Liver Foundation  
American Pancreatic Association  
American Society for  
Gastrointestinal Endoscopy  
American Society of Adults  
with Pseudo-Obstruction, Inc.  
Center for Ulcer Research and  
Education Foundation  
Colorectal Cancer Network  
Crohn's & Colitis Foundation  
of America  
Florida Gastroenterologic Association  
Hemochromatosis Foundation  
Hepatitis Foundation International  
International Foundation for  
Functional Gastrointestinal Disorders  
New York Society For  
Gastrointestinal Endoscopy  
North American Society for  
Pediatric Gastroenterology  
and Nutrition  
Pennsylvania Society of  
Gastroenterology  
Society of Gastroenterology  
Nurses and Associates, Inc.  
Stop Colon/Rectal Cancer Foundation  
United Ostomy Association  
Wound, Ostomy and  
Continence Nurses Society  
INSTITUTIONAL MEMBERS  
AstraZeneca LP  
Centocor, Inc.  
Glaxo Wellcome, Inc.

## ADMINISTRATION

Health & Medicine Counsel of  
Washington  
DALE P. DIRKS

Founder & President Emeritus  
Suzanne Rosenthal

Dear ladies & gentlemen :

I am writing to express our concern about recent events and media reports of adverse events involving patients who have taken Lotronex. One of our coalition members, the International Foundation for Functional Digestive Disease, already has commented to the FDA. We would like to add our collective voices in stating that this drug is an important advance in therapy for patients with diarrhea dependent irritable bowel syndrome. It is part of a new class of medications utilizing a better understanding of the molecular biology of the enteric nervous system. We are in an era where we can make a positive diagnosis of irritable bowel syndrome and begin multimodal therapy based upon a scientific understanding of the mechanisms involved in IBS. Symptoms range from inconvenient to disabling for those with IBS. The impact of IBS symptoms is comparable to other chronic diseases. Patients with severe symptoms have a very limited lifestyle complicated by severe diarrhea with urgency and the threat of fecal incontinence. There has been little to help them until this agent. It would be a mistake to limit the availability of this drug because of adverse events that are not clearly linked to proper use of the drug. The patients who used Lotronex and later developed complications were clearly not candidates for its use. The complication of constipation is well known and easily reversible. The etiology of ischemic colitis remains obscure and may be related to the age of the reported patients or other factors. We are concerned about patient safety, and we are also concerned that IBS patients have access to the best available, effective, and appropriate treatment.

OOP-1499

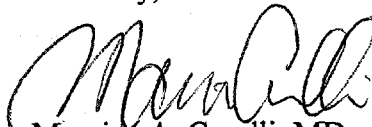
C 45

Therefore, we urge that decisions be made for or against the use of any drug in the face of adequate documentation, and hopefully after careful scientific and epidemiological investigation that involves experienced consultants. We hope that the FDA can activate the proper resources to answer questions of safety and efficacy accurately and expeditiously so that the IBS patient can best be served.

The DDNC is an advocacy organization comprised of 22 voluntary and professional societies concerned with the many diseases of the digestive tract and liver. Since its founding in 1978, the Coalition has worked in the public policy arena to increase public awareness, federal research funding and access to preventive services and life saving treatments for colorectal cancer, inflammatory bowel disease, viral hepatitis and other debilitating intestinal illnesses. Moreover, because the DDNC's membership includes a broad spectrum of both patient and professional organizations, we have been uniquely positioned to serve as a credible, consensus building organization within the digestive disease community.

Thank you for your consideration in this matter.

Sincerely,

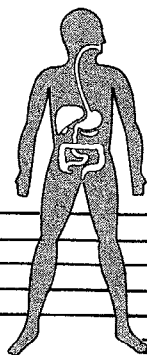
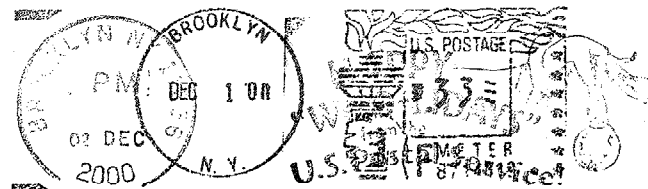


Maurice A. Cerulli, MD  
Voluntary President

## Digestive Disease National Coalition

7 Capitol Court, N.E., Suite 200  
Washington, D.C. 20002

urice A. Cerulli, MD



Dockets Management Branch  
Food and Drug Administration  
HFA-305, Room 1061  
5630 Fishers Lane  
Rockville, MD 20852

20837-0001

